AMENDMENT TO H.R. 4368, AS REPORTED

OFFERED BY MR. BIGGS OF ARIZONA

At the end of the bill (before the spending reduction account), insert the following:

SEC. _____. (a) None of the funds made available by this Act or otherwise made available to the Food and Drug Administration may be used to take an enforcement action on the basis that a homeopathic drug product is a new drug (as defined in section 201(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(p))) subject to the premarket approval requirements of section 505 of such Act (21 U.S.C. 355), provided that such homeopathic drug product complies with standards for strength, quality, and purity set forth in the Homeopathic Pharmacopoeia of the United States as provided in section 501(b) of such Act (21 U.S.C. 351(b)), absent an evidence-based determination by the Secretary that such drug product is unsafe.

(b) Nothing in this section shall be construed to prevent the use of funds for enforcement actions against products labeled homeopathic that fail to comply with section 501(a)(2)(B), 502, 503, or 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B), 352,

353, and 360), or standards for strength, quality, and purity set forth in the Homeopathic Pharmacopoeia of the United States as provided in section 501(b) of such Act (21 U.S.C. 351(b)).

(c) For the purposes of this section, the term ''homeopathic drug product'' means a drug product that—

(1) is labeled as ''homeopathic'';

(2) is labeled as containing only active ingredients and dilutions listed for those active ingredients in the Homeopathic Pharmacopoeia of the United States, an addendum to it, or its supplements; and

(3) contains no non-homeopathic active ingredient.